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APPLICATION NO.	PILING DATE FIRST NAMED INVENTOR			ATTORNEY DOCKET NO.	
		٦	EXAMINER		
			ART UNIT	PAPER NUMBER	
				16	
			DATE MAILED:		

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

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		Application No.	Applicant(s)				
Office Action Summary		09/515,363	FISHER ET AL.				
	Office Action Summary	Examiner	Art Unit				
		Bronwen M. Loeb	1636				
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status							
1)[	Responsive to communication(s) filed on <u>07 June 2001</u> .						
2a)[	This action is <b>FINAL</b> . 2b)⊠ Th	is action is non-final.					
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims							
4) Claim(s) 1-30 is/are pending in the application.							
4a) Of the above claim(s) is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6) Claim(s) is/are rejected.							
7) Claim(s) is/are objected to.							
8) Claims 1-30 are subject to restriction and/or election requirement.							
Application Papers							
9) The specification is objected to by the Examiner.							
10) The drawing(s) filed on is/are objected to by the Examiner.							
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved.							
12) The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. § 119							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) ☐ All b) ☐ Some * c) ☐ None of:							
1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
<ul> <li>Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).							
Attachment(s)							
15) Notice of References Cited (PTO-892)  18) Interview Summary (PTO-413) Paper No(s).  19) Notice of Draftsperson's Patent Drawing Review (PTO-948)  19) Notice of Informal Patent Application (PTO-152)							
17) 📙 Info	rmation Disclosure Statement(s) (PTO-1449) Paper No(s)	20)					

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## **DETAILED ACTION**

This action is in response to Paper #14, received June 6, 2001.

In the application transmittal letter dated February 29, 2000, it was indicated that a preliminary amendment was filed. No preliminary amendment was found in the case.

The claims, filed as 1-25 and 31-35 have been renumbered 1-30 in accordance with 37 CFR 1.126. Claims 1-30 are pending.

## Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-11, drawn to an isolated nucleic acid, classified in class 435, subclass 320.1.
  - II. Claims 12-20, drawn to a method for determining whether a compound is an inducer of Mda-5 gene expression in a cell, classified in class 435, subclass 4.
  - III. Claim 21, drawn to an isolated polypeptide, classified in class 530, subclass 350.
  - IV. Claims 22 and 23, drawn to an isolated antibody, classified in class 530, subclass 387.7.
  - V. Claims 24-28, drawn to a method for treating cancer, classified in class435, subclass 375.

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VI. Claims 29 and 30, drawn to an assay to determine whether a compound modifies enzymatic activity of an Mda-5 polypeptide, classified in class 435, subclass 4.

2. The inventions are distinct, each from the other because of the following reasons:
Inventions I, III and IV are distinct products from each other, having different
chemical, biological, structural and functional distinctness from each other, and are not
disclosed for use together.

Inventions II, V and VI are distinct methods from each other, having different starting material, different outcomes and different uses.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of claim II can be used with another materially different product, an antibody.

Inventions IV and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method of claim II can be used with another materially different product, a nucleic acid.

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Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the isolated polypeptide of invention III can be used to raise antibodies which is a materially different process of use.

Inventions I, V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the isolated nucleic acid of Invention I is not disclosed as capable of used with either of the processes of Inventions V and VI.

Inventions III, II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the isolated polypeptide of Invention III is not disclosed as capable of used with either of the processes of Inventions II and V.

Inventions IV, V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the isolated antibody of Invention IV is not disclosed as capable of used with either of the processes of Inventions V and VI.

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3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classifications, restriction for examination purposes as indicated is proper.

4. A telephone call was made to **John White** on **Feb. 14**, **2001** to request an oral election to the above restriction requirement, but did not result in an election being made. **Brian Amos** returned the call on the same day and requested a written restriction.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

## Conclusion

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the

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notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 9:30 AM to 6:00 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Dr. John LeGuyader, can be reached on (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to Dianiece Jacobs, Patent Analyst whose telephone number is (703) 305-3388.

Bronwen M. Loeb, Ph.D. Patent Examiner Art Unit 1636

June 22, 2001

ROBERT A. SCHWARTZMAN PRIMARY EXAMINER